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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 05/05/2004

12

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/974,782

Applicant(s)

HUBBARD ET AL.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 21, 23 and 46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-11, 13-17, 19, 20, 24-26, 28-36, 38-42, 44 and 45 is/are rejected.
- 7) ☒ Claim(s) 3, 12, 18, 27, 37, 40 and 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Election/Restrictions

Claims 21-23 and 46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Applicant's election with traverse of claims 1-20,24-45 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that there is not a meaningful burden to the Examiner and that the predecessor parent included both the product and process claims. This is not found persuasive because the invention are distinct if either (1) the process for using the product can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In this case the product may be used in a different surgical process of using which does not require the steps of the process of using as claimed.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6,15,30,40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6,15,30 and 40 fail to further define the structure of claim 2 from which it depends. Examiner disagrees with applicant's arguments that the function further

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defines the structure of the device. It is not clear how the functional recitation further defines the angle as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6-8, 10, 11, 15, 16, 19-24, 25, 26, 30, 31, 32, 33, 44, 45, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirshner in view of Forte (5092899).

Kirshner discloses all the features of the prosthetic component as claimed except for the slot formed along the long axis of the bone. To provide a slot in the stem of Kirshner to effect the correct flexibility that is comparable with the surrounding bone so as to prevent system failure would have been obvious from the teachings of Forte. With respect to applicant's arguments directed to Kirshner, examiner respectfully disagrees with applicant's reading of the reference. The osteocap hip as disclosed by Kirshner and illustrated in the Biomet publication is one and the same. Examiner is not using the teachings of the operative techniques in the application of the reference to the claimed invention. Rather, the Biomet reference is used merely to point out and better illustrate the 3-D profile of the prosthetic device. As illustrated in the Biomet publication, the C-2 Osteocap hip prosthesis includes a cone and funnel fit of the conical collar impedes the rotational forces and transforms it to a compressive loading force. The disclosure goes

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on to say that the 30 degree conical collar allow the distal stem to remain independent of the distally directed forces. Applicant failure to include the Biomet reference along with the current file does not remove this publication as a reference to the claimed invention. Examiner maintains that Kirshner in light of the Biomet disclosure, would not allow applicant any other reading of the shape of the collar as argued by applicant. Examiner does not rely on inherency but rather the specific disclosure of the Kirshner publication. Applicant apparent disregard of the entire disclosure of Kirshner incorrectly leads applicant to state that "the Kirshner drawing is a mere profile and does not reveal the structure of the undersurface of a terminal portion of the lip." Examiner has identified all facet of the claimed invention. If applicant has a different reading of the reference, then applicant should positively identify these differences based upon the entire disclosure of Kirshner. Mere possibilities of other configurations by applicant are not supported by the disclosure of Kirshner.

Claim 2, the flared plate surface (30 degrees) makes an angle of less than 180 degrees with the flared surface. Note, the medial surface of the stem flares from the central longitudinal axis.

Claim 6, see flared plate surface and stem means of Kirshner.

Claim 7, the claim is so worded that a lateral overhang is not positively claimed and therefor the claim fails to define over the plate surface of Kirshner.

Claim 8, the angle of the conical flared plate surface is 30 degrees which when added to 90 degrees forms the angle as claimed.

The C-2 Osteocap hip of Kirshner discloses the prosthesis as having a cone and funnel fit of the conical collar impedes the rotational forces and transforms it to a compressive loading force. The disclosure goes on to say that the 30degree conical collar allow the distal stem to remain independent of the distally directed forces. Moreover, figure 11 shows the reamer used to form the funnel shaped bone receiving surface to mate with a complementary shaped conical collar.

Claims 11 and 15, the flared plate surface (30 degrees) makes an angle of less than 180 degrees with the flared surface. Note, the medial surface of the stem flares from the central longitudinal axis.

Claim 16, see support plate of Kirshner showing medial, anterior and posterior portion of the flared plate section.

Claim 19 the prosthetic component of Kirshner is a femoral component.

Claim 20, the flared plate section forms a 30 degree angle with the second side.

Claims 21-23, see the surgical technique disclosed by Kirshner, particularly by Dr. Fenning.

Claim 24, see application of Kirshner as applied to claim 1 supra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,4-7,11,13-17,24,25,26,28-32,34,36,38,39-42 are rejected under 35 U.S.C. 102(e) as being anticipated by Noiles et al (6152963).

Noiles et al discloses a prosthetic component comprising an elongate stem having distal and proximal sections defining a long axis and a slot extending along the long axis. The prosthetic component further includes a support plate means having a first and second opposing sides. The first side including at least one flared plate surface having a medical section and flaring outwardly from the proximal section in a distal to proximal direction such that an under surface of a terminal portion of a lip of the medical section forms an angle with the long axis that is greater than 90 degrees. (See figures 1 and 3).

Claim 2, see figure 3 that illustrates a flared plate surface and a flared stem surface where the angle between the surfaces is less than 180 degrees.

Claim 4, see flared stem in figure 3.

Claim 5, see double flared contact as shown in figure 3.

Claim 6, see rejection to claim 1 supra.

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Claim 7, see overhang of the proximal section of the flared plate in figure 3.

Claim 11, see rejection to claim 2 supra.

Claim 13, see figure 3.

Claim 14, see double flared contact as shown in figure 3.

Claim 15, see claim 6 supra.

Claim 16, the flared plate section on the medial, anterior and posterior surfaces as shown in figure 3.

Claim 17, see flared stem means in figure 3.

Claim 19, the prosthetic component of Noiles, et al includes a femoral component.

Claim 24, see figure 3.

Claims 25,26,28-32,34,36,38,39-42 see rejections to the claims supra. Claim 25 is essentially identical to claim 1 including limitation to the stem means defining a non varying radius. This feature is shown in figure 3 by Noiles, et al.

Claim 26 is similar to claim 5 supra.

Claim 28 is similar to claim 13 supra.

Claim 29 is similar to claim 14 supra.

Claim 30 is similar to claim 6 supra.

Claim 31 see overhang in figure 3.

Claim 32, the angle as shown in Noiles et al falls with the range as claimed.

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Claim 34, defines a male corner between the proximal and distal portion of the stem. This feature is shown by Noiles, et al (see figure 3).

Claim 35 see abrupt configuration in figure 3. (Note bottom surface of section 18).

Claim 36 is similar to claim 5 supra.

Claim 38 is similar to claim 2 supra.

Claim 39 is similar to claim 5 supra.

Claim 40 is similar to claim 6 supra.

Claim 41 is similar to claim 13 supra.

Claim 42, see rejection to claim 32 supra.

Claims 44 and 45, see rejection to claim 1 supra.

Allowable Subject Matter

Claims 3,12,18,27,37,40,43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI

MAY 2, 2004